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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,216

06/02/2005

Daniel L. Mooradian

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INTELLECTUAL PROPERTY GROUP

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,216	<b>Applicant(s)</b> MOORADIAN ET AL.	
	<b>Examiner</b> Julian W. Woo	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/10/05, 7/29/05, 8/17/07</u> .                               | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-8 and 12-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 19-26 of U.S. Patent No. 7,128,748. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim a combination medical device and a kit for use with a circular stapling procedure, where the device and kit include, inter alia, a circular stapler instrument or stapler and portions of buttress material adapted to be positioned upon components of the stapler instrument or stapler.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 5, 6, 8-10, 12-14, 16, 17, 19-21, 23-25, 27, 28, 30-32, 34, 38, 39, 41, 42, 44-46, and 48-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Grant et al. (6,656,193). Grant et al. disclose, at least in figure 5 and in col. 5, lines 30-48 and col. 8, line 14 to col. 9, line 13; a combination medical device, kit, circular buttress material, and a method employing the device, where the device, kit, or circular buttress material comprises a circular stapler instrument (85), and one or more generally circular, preformed portions of pericardial, homogenous buttress material (86), where the buttress material is adapted to be positioned upon staple cartridge (87) and anvil (88) components of the stapler, be delivered to and positioned at a tissue site, and provide a first region of buttress material as a staple line buttress seal between joined tissue sections upon activation of the stapler; where one portion of the buttress material is adapted to fit the staple cartridge, and another portion is adapted to fit the anvil component; and where a first region of the buttress material serves as a staple line buttress, and a second region (one side of the buttress material facing a compression

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surface) is adapted to assist in positioning the material upon a stapler component, where the first and regions are generally concentric and provide a desired three dimensional structure adapted to position the materials in place upon respective stapler components, where the first and second regions of at least one buttress material comprises dissimilar materials or animal tissue and a polymer (i.e., a hot met adhesive composition, see, e.g., col. 8, lines 36-51), where a buttressed surgical seam between abutting tissue portions is created without first binding the tissue portions with one or more sutures, where attaching of first region to a second region (i.e., animal tissue to a polymer) includes adherence or tacking, and where the buttress material is a composite buttress material of two types of material (when the animal tissue is combined with a polymer,

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4, 15, 26, 37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant et al. (6,656,193) in view of Cooper et al. (5,503,638). Gabbay discloses the invention substantially as claimed, but does not disclose that the pericardium of the buttress material is formed by the process or method as claimed. Cooper et al. teach, in col. 3, lines 35-60 and in figure 1, the soaking of pericardium in a crosslinking solution and the shaping of the pericardium into a shape for use in a patient's body. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Cooper et al., to form the pericardium on a mandrel, to crosslink it in a solution, and to sterilize it. The use of a mandrel is a well-known way to form or shape resilient material, while crosslinking and sterilizing (another well-known process) the pericardium would decrease antigenicity and infection of tissue joined to the buttress material.

7. Claims 7, 11, 18, 22, 29, 33, 43, 47, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant et al. (6,656,193). Grant et al. disclose the invention substantially as claimed, but do not specifically disclose that one or more portions of the second region of the buttress material are adapted to be removed from a tissue site upon formation of a staple seam and activation of a stapler instrument knife. Nevertheless, the buttress material of Grant et al. is formed into sheet material that can be easily shaped into a desired configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to trim or cut the sheet material, including a second region, with a cutting instrument or a stapler instrument knife, so that the buttress material properly fits at a surgical site without

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excess portions. Also, Grant et al. do not specifically disclose that the animal or mammalian tissue is non-crosslinked. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply non-crosslinked mammalian tissue in the buttress material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

8. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant et al. (6,656,193) in view of Granger et al. (5,122,156). Grant et al. disclose the invention substantially as claimed, but do not disclose one or more retaining rings used to help retain abutting tissue portions on the buttress materials, where a tissue push tool to place the one or more retaining rings. Granger et al. teach, at least in figures 1, 3, 4, 11, and 12 and col. 6, lines 42-66; retaining rings (22) used to help retain abutting tissue portions, where a tissue push tool (10) is used to place a retaining ring. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Granger et al., to include retaining rings and a tissue push tool with the buttress materials and stapler instrument of Grant et al. Such a modification would allow the positioning and temporary securement of end portions of a tubular organ undergoing anastomosis before permanent securement of the end portions with staples from the stapler instrument.

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773